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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,463	02/26/2002	Wilma M Dausch	50683	3250

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1350 Connecticut Ave., NW
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EXAMINER

PENG, KUO LIANG

ART UNIT	PAPER NUMBER
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1712

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,463

Applicant(s)

DAUSCH ET AL.

Examiner

Kuo-Liang Peng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/6/05 Amendment.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 11-23 and 37-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 11-23 and 37-46 is/are rejected.
- 7) ☒ Claim(s) 43 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Applicants' amendment filed on April 6, 2005 was received. Claims 1-8, 10 and 24-36 are deleted. Claims 37-46 are added. Now, Claims 9, 11-23 and 37-46 are pending.
2. It is noted that the terminal disclaimer filed on April 6 2005 is improper because the signature is not from an attorney of record.
3. Claim objection(s) in the previous Office Action (Paper No. 1204) is/are removed. After further consideration, it is noted that "and" in Claim 9 (line 3) is proper.
4. Claim rejection(s) under 35 USC 102 in the previous Office Action (Paper No. 1204) is/are removed.
5. Claim rejection of Claim 17 under 35 USC 103 in the previous Office Action (Paper No. 1204) is removed because Applicants verify in the Remarks of the amendment filed on April 6 2005 that there is a common ownership of US 6

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191 215 and the present application at the time the present invention disclosed and claimed.

Claim Objections

6. Claims 43-44 are objected to because of the following informalities:

In Claim 43 (line 9), after “thereof, ”, should there be -- and --?

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 41-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 41, it is not clear as to “from 0.5 to 20% by weight” refers to the amount of component a), component b) or the mixture thereof.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 37-38 and 41-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In Claim 37 (lines 2-3), Examiner is not able to find the basis for the recited forms.

In Claim 41 (line 2), Examiner is not able to find the basis for “0.5 to 20% by weight”.

In Claim 43 (lines 2-3), Examiner is not able to find the basis for “polymer matrix”.

In Claim 45 (line 2), Examiner is not able to find the basis for “from 5 to 200 μm ”.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Blakenburg.

Blakenburg discloses a preparation obtained by free-radical polymerization of a monomer mixture of a) ethylenically unsaturated monomers and b) polyalkylene oxide-containing silicone derivatives of formula (I) (page 2, lines 16-25, page 10, line 24 to page 11, line 46 and Examples). The polymerization can be carried out in the presence of other polymers (page 9, lines 19-26). Blakenburg is silent on the use of the composition as a pharmaceutical preparation. However, Blakenburg's composition reads on the composition of the instant claim, it should be able to function as a pharmaceutical preparation, too. *In re Best*, 195 USPQ 430 (CCPA 1977). Note that "for being applied to skin or to a mucous membrane" is merely an intended use, and does not carry any weight of patentability. See MPEP 2111.02. The amounts of all components are further exemplified in Examples.

Claim Rejections - 35 USC § 103

13. Rejection of Claims 9, 11-16 and 18-23 under 35 USC 103(a) as being unpatentable over Blakenburg (WO 99/04750) in view of Sramek (US 4 871 529) and Habeck (JP 10-158140) is maintained because the rejection is adequately set forth in paragraph 5 of Paper No. 0104. The newly added Claims 37-38 and 45-46 are unpatentable over Blakenburg in view of Sramek and Habeck too. It is noted that there is a typographical error in paragraph 6 of the previous Office action (Paper No. 1204) where “Beckham” in line 2 should read “Blakenburg (WO 99/04750)”. Examiner apologizes for causing any incontinence. However, paragraph 6 of the previous Office action (Paper No. 1204) clearly refers to paragraph 5 of Paper No. 0104. Applicant's arguments have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below.

Applicants primarily argue that the use of the copolymer derived from *t*-butyl acrylate and methacrylic acid in the presence of [polyalkylene] oxide containing silicones in the present invention (i.e., Claim 9) has an unexpected good result over the use of polyvinyl lactam polymers alone. (Remarks, page 2, 4th paragraph to page 3, 2nd paragraph) However, Applicants should notice that first of

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all, Claim 9 does not limited to the copolymer derived from *t*-butyl acrylate and methacrylic acid in the presence of polyalkylene oxide containing silicones.

Secondly, the aforementioned unexpected result is irrelevant because Claim 9 is not limited to the use of polyvinyl lactam polymers only. Thirdly, the copolymers used for showing the unexpected result are limited to those copolymers derived from *t*-butyl acrylate, methacrylic acid, ethyl acrylate and *t*-butyl perivalate in the presence of polyalkylene oxide containing silicones (Examples 1-6), rather than copolymers derived from only *t*-butyl acrylate and methacrylic acid in the presence of polyalkylene oxide containing silicones. In other words, there is no evidence that formation of poly(*t*-butyl acrylate-co-methacrylic acid) in the presence of polyalkylene oxide containing silicones will result in the same unexpected result. Fourthly, as indicated in Applicants Remarks, the unexpected good results are solely demonstrated between a preparation containing Luviflex Silk and polyvinyl lactam polymers and a preparation containing polyvinyl lactam polymers alone. There is no evidence of unexpected result based on a preparation containing Luviflex Silk and other polymers claimed in the present invention and a preparation of these "other polymers" alone. For Claims 37-38, Blakenburg discloses a hair spray, lotion, etc. (page 12, lines 26-42) For Claims 45-46, note that Blakenburg's spray, etc. can be coated on the hair, skin, etc. The thickness of

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the coating can affect the effect of the treatment, protection, feeling, etc. of the substrates. In other words, the coating thickness is a Result-Effective variable.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to coat the substrate with whatever thickness through routine experimentation in order to have desired effect on the substrates.

Especially, Applicants do not show the criticality of the coating thickness. See MPEP 2144.05 (II). Note that “pharmaceutical” is merely an intended use, and does not carry any weight of patentability. See MPEP 2111.02. Especially, there is not any component recited in the instant claim rendering the instant preparation as a pharmaceutical preparation.

14. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blakenburg in view of Sramek and/or Habeck.


Blakenburg in view of Sramek and/or Habeck discloses a cosmetic preparation as described in paragraph 5 of Paper No. 0104, which is incorporated herein by reference. Note that “pharmaceutical” is merely an intended use, and does not carry any weight of patentability. See MPEP 2111.02. Especially, there is not any component recited in the instant claim rendering the instant preparation as a pharmaceutical preparation.

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15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

klp
July 15, 2005


Kuo-Liang Peng
Primary Examiner
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